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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/166,701	10/05/1998	ISA ODIDI	SMI-005.01	9432

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EXAMINER
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WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/166701

Applicant(s)

ODID1

Examiner

WEBMAN

Group Art Unit

1617

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

☒ Responsive to communication(s) filed on 11/8/02

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

☐ Claim(s) 1, 4, 7-12, 23, 28-33 is/are pending in the application.

Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 4, 7-12, 23, 28-33 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some\* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

☐ Copies of the certified copies of the priority documents have been received

in this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other \_\_\_\_\_

Office Action Summary

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 7-12, 23, 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guley et al in view of Jain et al.

Guley et al teach a controlled release (tablet) core comprising 20-70% drug and a 30-72% mixture of water soluble and water-insoluble polymers at ratio of 10:1-1.5:1

(column 2 lines 27-36). Hydroxypropyl cellulose and carboxyl vinyl polymer are specified (column 3 line 19). Etodolac is specified (column 4, line 67). Lactose is disclosed (column 5 example 1). Sustained release is specified (Title).  
*column 2 lines 42 and 48-49). A core comprising cellulose acetate phthalate is disclosed*

Guley et al further teach plural water-soluble polymers including hydroxypropyl methylcellulose and hydroxy propyl cellulose (column 2 lines 40-44). Plural water-insoluble polymers are specified including ethyl cellulose and carboxyl vinyl polymer (column 2 lines 45-50).

Jain et al teach the equivalence of cellulose alkyl hydroxylates in (Tablet) cores, in particular that of hydroxypropyl cellulose and hydroxyl Ethyl cellulose (column 5 lines 21-27).

It would have been obvious to one of ordinary skill to make a core comprising a carboxyl vinyl polymer, and alkyl cellulose in view of Guley et al. As to the claimed hydroxy ethyl cellulose, Jain et al teach the equivalence of this hydroxypropyl cellulose of Guley et al in tablet cores.

As to the claimed "about less than" and ingredients, such "up to about" limitations includes zero.

As to the claimed crosslinkers, applicants disclose that carbapol contains such (Page 4, lines 27-31).

No claims allowed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4, 8, 23, 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Skinner.

Skinner teaches a sustained release composition comprising hydroxyethyl cellulose and hydroxypropyl methyl cellulose (Title, Abstract).

Ibuprofen is disclosed (col. 3 line 55). As to the ingredients, <sup>other claimed</sup> ~~other claimed~~ "up to" includes zero.  
^

Claims 1, 4, 7, 18, 23, 28, 29, 32, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skinner in view of Guley et al.

Skinner is discussed above.

Guley et al discloses cellulose acetate phthalate as an enteric coating.

It would have been obvious to one of ordinary skill to coat the composition of skinner to with cellulose acetate phthalate to achieve the beneficial effect of an enteric coating. *in view of Guley et al.*

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday from 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR

March 1, 2002